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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,412	03/25/2004	Kaoru Asano	11333/35	8939

7590 06/14/2006
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EXAMINER

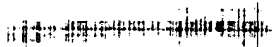
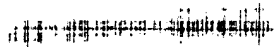
TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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Office Action Summary	Application No. 10/810,412	Applicant(s) ASANO ET AL.	
	Examiner Karen E. Toth	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22, 24-29, 32, 34-35 is/are rejected.
- 7) ☒ Claim(s) 21,23,30,31 and 33 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/25/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Conn'414 (US Patent 6438414).

Regarding Claim 1, Conn'414 discloses a device comprising a first electrode part (elements 4, 8 and 12) having a contact area of less than about 50 mm² (column 18, lines 4-6); a second electrode part (element 14); and a component to supply power to the first and second electrodes in order to extract an analyte (column 15, lines 24-36).

Regarding Claim 2, Conn'414 further discloses that the contact area may be about 25 mm² (column 18, lines 4-6), because .3 cm² (30 mm²) is about 25 mm².

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Regarding Claim 4, Conn'414 further discloses that the power supply part supplies a current of less than about 300 uA (column 15, lines 38-39).

Regarding Claim 5, Conn'414 further discloses that the first electrode part comprises an electrode connected to the power source (element 14), and a collection material (elements 4 and 8) that is connected to the electrode (column 15, lines 29-36).

Regarding Claim 6, Conn'414 further discloses that the collection material is in contact with the patient's skin (column 3, lines 54-59).

Regarding Claim 7, Conn'414 further discloses that the electrode part is detachable from the power supply part (column 15, lines 24-25), since a non-rechargeable battery must be removed (detached) in order to allow replacement.

Regarding Claim 13, Conn'414 further discloses that the power supply part may be a constant-voltage power supply (column 15, lines 24-25), because a battery supplies constant voltage.

Regarding Claim 15, Conn'414 further discloses that the device may comprise a part for accelerating or promoting analyte extraction (column 8, line 64 - column 9, line 7).

Regarding Claim 17, Conn'414 further discloses that the analyte is glucose (column 16, lines 39-43).

Regarding Claim 18, Conn'414 further discloses that the overall system comprises an assay part for assaying the analyte extracted in the first electrode part and for outputting a signal corresponding to the analyte's concentration (column 16, lines 31-38); an analysis part for analyzing the concentration signal

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(column 18, lines 42-50); and an output part for outputting the analysis result (column 18, lines 47-48).

Regarding Claim 24, Conn'414 discloses a method comprising placing two electrode parts on skin, one of which has a contact area of less than about 50 mm² (column 15, lines 24-34; column 18, lines 4-6); applying electrical energy to the electrode parts (column 15, lines 27-34); and extracting analyte at the first electrode part (column 15, lines 34-36).

Regarding Claim 25, Conn'414 further discloses that the contact area may be about 25 mm² (column 18, lines 4-6).

Regarding Claim 28, Conn'414 further discloses that the method comprises outputting a signal corresponding to the analyte's concentration (column 16, lines 31-38); analyzing the concentration signal (column 18, lines 42-50); and outputting the analysis result (column 18, lines 47-48).

Regarding Claim 29, Conn'414 discloses a method comprising forming analyte transmission paths in skin (column 9, lines 3-7); placing a through-current electrode part and a first electrode part on skin (column 15, lines 24-34; column 18, lines 4-6); applying electrical energy to the electrode parts (column 15, lines 27-34); and extracting analyte at the first electrode part (column 15, lines 34-36).

Regarding Claim 35, Conn'414 further discloses that the method comprises outputting a signal corresponding to the analyte's concentration (column 16, lines 31-38); analyzing the concentration signal (column 18, lines 42-50); and outputting the analysis result (column 18, lines 47-48).

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3. Claims 19-20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim'777 (US Patent 6736777).

Regarding Claim 19, the examiner notes that the device of Kim'777 is capable of being used as claimed because the device comprises a first electrode (element 40) with an area of less than 50 mm^2 (column 16, lines 65-67); an electrode for extracting an analyte (element 42); a through-current electrode (element 44); and a power supply used to supply power to all the electrodes (column 18, lines 11-20).

Regarding Claim 20, Kim'777 further discloses that the contact area may be about 25 mm^2 (column 16, lines 65-67), because 0.3 cm^2 (30 mm^2) is about 25 mm^2 .

Regarding Claim 22, Kim'777 further discloses a second path-forming electrode (element 41) with an area of less than 50 mm^2 (column 16, lines 65-67); a second electrode for extracting an analyte (element 43); a second through-current electrode (element 45); and a power supply used to supply power to all the electrodes (column 18, lines 11-20).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 3, 8-11, 26-27, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn'414 in view of Avrahami'227 (US Patent Application Publication 2004/0230227).

Regarding Claim 3, Conn'414 discloses all the elements of the current application, as applied to claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35 above, except for the current flowing from the power supply part, through the through-current electrode into the skin, then into the first electrode part and finally back to the power supply part.

Avrahami'227 discloses a transdermal analyte extraction device comprising a through-current electrode and a first electrode (elements 120 or 124) and a power supply (elements 50 and 98), wherein the current flows from the power supply part, through the through-current electrode into the skin, then into the first electrode part and finally back to the power supply part (Figure 4), in order to more efficiently extract analytes.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn'414 with the specific current flows of Avrahami'227, in order to more efficiently extract analytes.

Regarding Claim 8, Conn'414 discloses all the elements of the current application, as applied to claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35 above, except for the device comprising a second electrode part having the same contact area as the first electrode part, and the power supply part of the device comprising power supplies for both the first and second electrode parts.

Avrahami'227 discloses a transdermal analyte extraction device comprising a plurality of identical electrode parts (Figure 2), each with a power supply (Figure 4), in order to more thoroughly sample analytes from a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn'414, with additional electrodes, each with a power supply, as taught by Avrahami'227, in order to more thoroughly sample analytes from a patient.

Regarding Claim 9, the plurality of duplicate electrode parts comprising the device of Conn'414 in view of Avrahami'227 may have a contact area of about 25 mm² (column 18, lines 4-6), because .3 cm² (30 mm²) is about 25 mm².

Regarding Claim 10, the plurality of duplicate electrode parts comprising the device of Conn'414 in view of Avrahami'227 may each comprise an electrode (element 14) connected to the power part and an analyte collection material (elements 4 and 8) that contacts the electrode (column 15, lines 29-36).

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Regarding Claim 11, Conn'414 in view of Avrahami'227 discloses all the elements of the current invention except for the first and second electrode parts being integrated.

Avrahami'227 further discloses that the plurality of electrode parts are integrated within a single housing (Figure 2), in order to facilitate application upon a patient's skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn'414 in view of Avrahami'227, and integrated the electrode parts, as taught by Avrahami'227, in order to facilitate application upon a patient's skin.

Regarding Claim 26, Conn'414 discloses all the elements of the current invention, as applied to claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35 above, except for the method comprising placing a second electrode part having the same contact area as the first electrode part on the skin, supplying it with electrical energy, and extracting analyte at the duplicate electrode.

Avrahami'227 discloses a method of transdermal analyte extraction comprising a placing a plurality of identical electrode parts (Figure 2) on a patient's skin, each with a power supply (Figure 4), and using them to transdermally extract analyte, in order to more thoroughly sample analytes from a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Conn'414, with the steps of

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adding, powering, and sampling from additional electrodes, as taught by Avrahami'227, in order to more thoroughly sample analytes from a patient.

Regarding Claim 27, Conn'414 in view of Avrahami'227 discloses all the elements of the current invention, as disclosed above, except for the first and second electrode parts being placed on the skin substantially simultaneously.

Avrahami'227 further discloses that the plurality of electrode parts are disposed within a single housing (Figure 2) and are therefore placed on the skin substantially simultaneously, in order to more efficiently apply the sampling apparatus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Conn'414 in view of Avrahami'227, and applied the electrode parts simultaneously, as taught by Avrahami'227, in order to more efficiently apply the sampling apparatus.

Regarding Claim 32, Conn'414 discloses all the elements of the current invention, as applied to Claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35 above, except for the method comprising placing a second extraction electrode part on the skin, supplying it with energy, and using it to extract analyte.

Avrahami'227 discloses a method of transdermal analyte extraction comprising a placing a plurality of identical electrode parts (Figure 2) on a patient's skin, each with a power supply (Figure 4), and using them to transdermally extract analyte, in order to more thoroughly sample analytes from a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Conn'414, with the steps of adding, powering, and sampling from additional electrodes, as taught by Avrahami'227, in order to more thoroughly sample analytes from a patient.

Regarding Claim 34, Conn'414 in view of Avrahami'227 discloses all the elements of the current invention, as disclosed above, except for the first and second electrode parts being placed on the skin substantially simultaneously.

Avrahami'227 further discloses that the plurality of electrode parts are disposed within a single housing (Figure 2) and are therefore placed on the skin substantially simultaneously, in order to more efficiently apply the sampling apparatus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Conn'414 in view of Avrahami'227, and applied the electrode parts simultaneously, as taught by Avrahami'227, in order to more efficiently apply the sampling apparatus.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conn'414 in view of Glikfeld'543 (US Patent 5279543).

Conn'414 discloses all the elements of the current invention, as applied to claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35 above, except for the power supply part outputting a voltage of less than about 10 V.

Glikfeld'543 teaches a device comprising a pair of electrodes for extraction of an analyte, where the power supplied by a power supply part is less than

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about 10 V (column 7, lines 63-64), in order to prevent harm to the patient from excess voltage.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn'414 and used the power supply part to output a voltage of less than about 10 V, as taught by Glikfeld'543, in order to prevent harm to the patient from excess voltage.

7. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn'414 in view of Ackerman'114 (US Patent Application Publication 2003/0208114).

Regarding Claim 12, Conn'414 discloses all the elements of the current invention, as applied to claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35 above, except for the power supply part supplying constant current.

Ackerman'114 discloses a device for transdermal analyte extraction comprising a part to supply direct (constant) current, in order to facilitate analyte extraction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn'414, with a constant current power supply, as taught by Ackerman'114, in order to facilitate analyte extraction.

Regarding Claim 16, Conn'414 discloses all the elements of the current invention, as applied to claims 1-2, 4-7, 13, 15, 17-22, 24-25, 28-29, and 35

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above, except for the extraction acceleration part comprising ultrasonic irradiation.

Ackerman'114 discloses a device for transdermal analyte extraction comprising a part to apply ultrasonic irradiation, in order to facilitate analyte extraction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn'414 with the part for applying ultrasonic irradiation, as taught by Ackerman'114, in order to facilitate analyte extraction.

Allowable Subject Matter

8. Claims 21, 23, 30-31, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the structure of Claims 21 and 23, including, *inter-alia*, connecting the path-forming electrode part only during path forming, and disconnecting it when extracting analyte.

The prior art of record fails to anticipate or make obvious the structure of Claims 30-31 and 33, including, *inter-alia*, placing a path-forming electrode on the skin and powering it in order to create transmission paths for analyte.

Conclusion

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9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6201979 to Kurnik, which discloses a device for transdermal extraction.

US Patent 5771890 to Tamada, which discloses a device for transdermal extraction.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ROBERT L. NASSER
PRIMARY EXAMINER